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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/815,341	03/22/2001	Nancy J. Bump	BBI-6069	4413

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EXAMINER	
SMITH, CAROLYN L	14

ART UNIT	PAPER NUMBER
1631	

DATE MAILED: 03/10/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/815,341	BUMP ET AL.	
	Examiner	Art Unit	
	Carolyn L Smith	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-88 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-88 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

The art unit designated for this application has changed. Applicant(s) are hereby informed that future correspondence should be directed to Art Unit 1631.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-2 and 88, drawn to a crystalline polypeptide, classified in classe 530, subclass 350.

II. Claims 3-14, drawn to a crystalline polypeptide-ligand complex, classified in class 530, subclasses 300 and 350. If this Group is elected, then the below summarized specie election is also required.

III. Claims 15-20, drawn to a method for determining the three-dimensional structure of first polypeptide comprising the catalytic domain of a Tie-2 protein, classified in class 702, subclass 27.

IV. Claims 21-35, drawn to a method of identifying an inhibitor compound of a Tie-2 protein, classified in classes 702 and 435, subclasses 19 and 7.1, respectively. If this Group is elected, then the below summarized specie election is also required.

V. Claims 36-58, drawn to a method of identifying a potential inhibitor of a Tie-2 protein, classified in class 702, subclass 19. If this Group is elected, then the below summarized specie election is also required.

VI. Claims 59-75, drawn to a Tie-2 inhibitor, classified in class 514, subclass 1. If this Group is elected, then the below summarized specie election is also required.

VII. Claims 76-83, drawn to a method of treating a Tie-2 dependent condition in a patient, classified in class 514, subclass 2. If this Group is elected, then the below summarized specie election is also required.

VIII. Claim 84, drawn to a method of decreasing fertility in a patient, classified in class 514, subclass 1. If this Group is elected, then the below summarized specie election is also required.

IX. Claim 85-86, drawn to a method of promoting angiogenesis or vasculogenesis in a patient, classified in class 514, subclass 1. If this Group is elected, then the below summarized specie election is also required.

X. Claim 87, drawn to a method of determining the three-dimensional structure of a polypeptide containing the catalytic domain of Tie-2 protein, classified in class 702, subclass 19.

Specie Election Requirement for Groups II and IV-IX:

This application contains claims directed to patentably distinct species of the claimed invention for the following Groups:

For Groups II and IV:

These Groups contain patentably distinct species of the claimed inventions, namely ligands. Therefore, if one of these Groups is chosen, a specific ligand structure is requested (such as one from claims 7, 9, 11, or 13 for Group II or claims 28, 30, 32, or 34 for Group IV) to be used for the initial examination of this application.

For Group V:

This Group contains patentably distinct species of the claimed inventions, namely crystal structural coordinates. Therefore, if this Group is chosen, a specific set of crystal structural coordinates is requested (such as one from Figures 3 through 6) to be used for the initial examination of this application.

For Groups VI-IX:

These Groups contain patentably distinct species of the claimed inventions, namely Tie-2 inhibitor compounds. Therefore, if one of these Groups is chosen, a specific Tie-2 inhibitor and specifically listing the 2 or more characteristics listed in (a) – (t) in claim 59 is requested to be used for the initial examination of this application.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. This distinctness of these ligand, crystal structure coordinates, and inhibitor compound species is because they are directed to different chemical types regarding the critical limitations therein. The completely separate chemical and entity types of these species are often separately characterized and published in literature, thus adding to the search burden if both species were examined together. Also, processing that may connect these species does not prevent them from being considered distinct because enough processing can result in the production of any composition from another composition as long as the processing is not limited in occurrences such as subtractions, additions, and enzymatic action. Thus, the above-mentioned species are distinct invention types for restriction purposes.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

The inventions are distinct, each from the other because of the following reasons:

The inventions of Groupings [I-V and X] and [VI-IX] are independent inventions because they are directed to different chemical and entity types regarding the critical limitations therein. For Groups I-V and X, the critical feature is a crystalline polypeptide. For Groups VI-IX, the critical feature is a Tie-2 inhibitor. The completely separate chemical and entity types of the invention Groups are often separately characterized and published in literature, thus adding to the search burden if all Groups were examined together. Also, processing that may connect two

Groups does not prevent them from being considered distinct because enough processing can result in the production of any composition from another composition as long as the processing is not limited in occurrences such as subtractions, additions, and enzymatic action. Thus, the two Groupings [I-V and X] and [VI-IX] are independent and/or distinct invention types for restriction purposes.

Inventions in Groups I-V and X are related as product and the process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the crystalline polypeptide of Group I may be utilized in distinct usages as needed in Group II for a crystalline polypeptide-ligand complex, in a method for determining the three-dimensional structure of first polypeptide as in Group III, in a method of identifying an inhibitor of a Tie-2 protein via testing compounds as in Group IV, in a method of identifying a potential inhibitor of a Tie-2 protein via designing compounds as in Group V, in a method of determining the three-dimensional structure of a polypeptide containing the catalytic domain of a Tie-2 protein as in Group X, or alternatively, in a pharmaceutical composition. All of these usages are distinct as requiring distinct and different functions thereof without overlapping search due to different subject matter. This lack of overlapping searches documents the undue search burden if they were searched together.

Inventions in Groups VI-IX are related as product and the process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the

product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the Tie-2 inhibitor of Group VI may be utilized in distinct usages as needed in Group VII for a method of treating a Tie-2 dependent condition in a patient, in a method of decreasing fertility in a patient as in Group VIII, in a method of promoting angiogenesis or vasculogenesis in a patient as in Group IX, or alternatively, in screening for receptor modulators. All of these usages are distinct as requiring distinct and different functions thereof without overlapping search due to different subject matter. This lack of overlapping searches documents the undue search burden if they were searched together.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement may be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the

Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR §1.6(d)). The CM1 Fax Center number is either (703) 308-4242 or (703) 305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carolyn Smith, whose telephone number is (703) 308-6043. The examiner can normally be reached Monday through Friday from 8 A.M. to 4:30 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on (703) 308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instruments Examiner Tina Plunkett whose telephone number is (703) 305-3524 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

March 3, 2003

ARDIN H. MARSCHEL
PRIMARY EXAMINER